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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,810	03/01/2002	Isabelle Arnould	1721-39	8335

23117 7590 01/22/2004

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EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,810	ARNOULD ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 OCT 04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL REJECTION

1. The applicant's Response (filed 03 OCT 03) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-4 and 6-7** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 112- 2ND PARAGRAPH

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 6-7** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is drawn to a method for studying the profiles of expression of the genes present in a tissue or in cells, characterized in that it comprises contacting cDNA mixtures according to Claim 4 with DNA of said tissues. **Claim 7** is drawn to a method for identify a tissue-specific DNA sequence which comprises hybridizing (i.e. contacting) cDNA mixtures with DNA of one or more tissues.

It is unclear to the examiner how one can study the expression of genes (or identify a tissue-specific DNA sequence) by hybridizing (i.e. contacting) a cDNA mixtures with DNA of one or more tissues. The DNA in every tissue of a particular subject species will be identical. Perhaps the applicant intended the word "DNA" to be "mRNA" or DNA corresponding to gene sequences or perhaps some essential step(s) have not been recited. Please clarify.

35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> **(e)** The invention was described in –
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

Claim Rejections under 35 USC § 102

5. **Claim(s) 1-2, 4** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Weissman et al. [4,738,928 (1988)].

Weissman et al. teach a method of producing a complex mixture of cDNA as recited in Claims 1-2. See, for example, Column 4, beginning at about line 17.

Response to Applicant's Amendment/ Arguments

6. Applicant's arguments with respect to the rejection of Claim(s) 1-2 under 35 U.S.C. 102(b) as anticipated by Weissman et al. [4,738,928 (1988)] have been fully and carefully considered but are not deemed to be persuasive.

As argued above, Weissman et al. teach a method of producing a complex mixture of cDNA as recited in Claims 1-2.

The applicant argues that their invention is different from Weissman et al. because the cited patent relates to a method for cloning genes wherein the mRNA corresponding to the gene is present in very low amount in a mRNA mixture, and state that "Contrary to the present invention, the addition of

elongation terminators is not carried out for obtaining a cDNA mixture representing the number and the level of expression of genes extracted from the tissue or the cell to be studied. This argument has been fully and carefully considered but is not deemed to be persuasive. The applicant appears to be pointing out limitations not present in the claims. While the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections under 35 USC § 102

7. **Claim(s) 1-2, 4** is/are rejected under 35 U.S.C. 102(a) as being anticipated by DeCaraene et al. (NOV 1999).

Decraene et al. teach a method of producing a complex mixture of cDNA as recited in Claims 1-2. In addition, Decraene et al. teach the cDNA mixtures as recited in Claim 4, as well as, their use in hybridization experiment to analyze gene expression.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

8. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are not deemed to be adequate to overcome the rejection.

The applicant argues that the rejection of **Claim(s) 1-2, 4** under 35 U.S.C. 102(a) as being anticipated by DeCaraene et al. (NOV 1999) should be withdrawn as the cited document was published after the filing of the applicants' presently claimed priority document. The applicant states that an English translation of the priority document will be filed under separate cover once received by the undersigned. In response: as the translation has not been received /reviewed by the examiner as of this action, the rejection has been maintained. Of course, once the priority claim has been perfected this rejection will be withdrawn.

35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

11. **Claim(s) 3** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman et al. [4,738,928 (1988)] as applied against Claim 1 above and further in view of the GeneAmp Reagent Kit / Instructions for Use (1988).

Weissman et al. teach a method requiring all of the elements recited in Claim 3 except these authors do not explicitly teach incorporating the reagent necessary to perform their method(s) into a kit. However, as evidenced by GeneAmp Reagent Kit / Instructions for Use, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Weissman et al. with the teachings of the GeneAmp Reagent Kit / Instructions for Use wherein the reagents necessary to perform the method(s) taught by of Weissman et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits when performing the method(s) taught by Weissman et al.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

12. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are not deemed to be persuasive.

The applicant argues that the rejection of **Claim(s) 3** under 103(a) as being unpatentable Weissman et al. [4,738,928 (1988)] as applied against Claim 1 above and further in view of the GeneAmp Reagent Kit / Instructions for Use (1988) should be withdrawn as the secondary reference fails to cure the deficiencies noted above with regard to the cited patent. As noted above, the previous argument has been fully and carefully considered but is not deemed to be persuasive.

CLAIM REJECTIONS UNDER 35 USC § 103

13. **Claim(s) 3** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Decraene et al. (NOV 1999) as applied against Claim 1 above and further in view of the GeneAmp Reagent Kit/ Instructions for Use (1988).

Decraene et al. teach a method requiring all of the elements recited in Claim 3 except these authors do not explicitly teach incorporating the reagent necessary to perform their method(s) into a kit. However, as evidenced by GeneAmp Reagent Kit / Instructions for Use, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Decraene et al. with the teachings of the GeneAmp Reagent Kit / Instructions for Use wherein the reagents necessary to perform the method(s) taught by of Decraene et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits when performing the method(s) taught by Decraene et al.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

14. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are not deemed to be adequate to overcome the rejection.

The applicant argues that the rejection of **Claim(s) 3** under 103(a) as being unpatentable over Decraene et al. (NOV 1999) as applied against Claim 1 above and further in view of the GeneAmp Reagent Kit/ Instructions for Use (1988) should be withdrawn as the cited document [i.e.Decraene et al. (NOV 1999)] was published after the filing of the applicants' presently claimed priority document. The applicant states that an English translation of the priority document will be filed under separate cover once received by the undersigned. In response: as the translation has not been received /reviewed by the examiner as of this action, the rejection has been maintained. Of course, once the priority claim has been perfected this rejection will be withdrawn.

CONCLUSION

15. **Claim(s) 1-6** is/are rejected and/or objected to for the reason(s) set forth above.

16. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

♦Please note that the USPTO is scheduled to relocate to its new home in Alexandria, VA very soon (JAN 04'). As a result, the examiner's telephone and desktop FAX numbers will be changing. The new telephone and desktop FAX numbers for Ethan Whisenant, Ph.D. are/will be as shown below:
New Telephone number : (571) 272-0754
New FAX number : (571) 273-0754.

ETHAN WHISENANT
PRIMARY EXAMINER

Art Unit 1634